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UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

MULTIPLE ENERGY TECHNOLOGIES LLC, Plaintiff, v. HOLOGENIX, LLC, Defendant.	**Civil Action No.** **COMPLAINT FOR VIOLATION OF THE LANHAM ACT; INTENTIONAL INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE; NEGLIGENT INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE** **JURY TRIAL DEMANDED**

Plaintiff Multiple Energy Technologies LLC ("MET") hereby alleges the following against Defendant Hologenix, LLC ("Hologenix"):

1. This action arises out of Hologenix's advertising and promotion of a bioceramic material branded as Celliant®.

2. Bioceramics may be woven into, printed on, or embedded in sportswear, sleepwear, bedding, and other textiles. If designed and implemented correctly, bioceramics incorporated into textiles will reflect a person's heat back to his or her body as infrared energy.

3. Hologenix has attempted to differentiate Celliant from other bioceramics in the market, and specifically from MET's Redwave®-branded product, through a multifaceted advertising campaign of false and deceptive statements. According to Hologenix's marketing and advertising materials, its bioceramic material (and no other) has been "approved" by the Food and Drug Administration ("FDA"), and products incorporating Celliant were "determined" by the FDA to be medical devices and wellness products "because they promote increased local blood flow at the site of application in healthy individuals." Celliant, Facebook (July 25, 2017), https://www.facebook.com/Celliant/photos/good-news-celliant-fans-the-us-food-and-drug-administration-has-determined-celli/10154876779297817/ S*ee* Exh. A.

4. These statements are false and misleading. The FDA has not approved Celliant. The FDA has not "determined" anything about the actual health benefits, if any, of products containing Celliant.

5. Compounding these falsehoods, Hologenix's advertising campaign includes numerous claims about the purported health benefits of Celliant alongside the false and misleading "FDA-approved" and "FDA-determined" messages to convey the false impression that the FDA has validated Hologenix's health claims.

6. For example, in the same promotional materials in which Hologenix advertises Celliant as "FDA-approved" and/or an "FDA-determined" medical device and wellness product, Hologenix describes certain alleged benefits of using products containing Celliant, such as better sleep, improved athletic performance, faster healing from injury, faster recovery from physical activity, decreased pain, increased cognitive ability, and greater stamina and endurance.

7. Hologenix's health claims are not supported by competent and reliable tests of products containing Celliant, further contributing to the misleading and deceptive nature of Hologenix's campaign.

8. Not only does Hologenix make these statements directly, but Hologenix also encourages its partners to make these statements and ratifies the same types of false and misleading statements about Celliant when made by third parties.

9. As a whole, Hologenix's campaign has been highly effective. Journalists throughout the country are reporting about Hologenix's "first of its kind" "FDA approved" bioceramic.

I. THE PARTIES

10. Plaintiff Multiple Energy Technologies LLC is a Delaware limited liability company, having its principal place of business at 470 Johnson Road, Suite 220, Meadow Pointe Plaza, Washington, PA 15301.

11. Dr. Shannon Vissman began operating MET in May 2012.

12. Dr. Vissman and his team developed and tested a bioceramic powder branded as "Redwave™."

13. MET sells Redwave powder to manufacturers that print Redwave onto their garments, sheets, and other textiles and then, in turn, sell those products to consumers.

14. Defendant Hologenix, LLC is a Delaware limited liability company, having its principal place of business at 227 Broadway, Santa Monica, CA 90401.

15. Hologenix makes a bioceramic material branded as "Celliant." Hologenix sells Celliant as a fiber that its manufacturer partners weave into fabrics. *See How Celliant Is Made,* Celliant, https://celliant.com/how-its-made/ (last visited Feb. 20, 2019). Upon information and belief, Hologenix also sells Celliant to Under Armour, Inc., as a powder.

II. JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. § 1331 and 15 U.S.C. § 1121(a) because this action arises under the laws of the United States, Chapter 22 of Title 15. This Court has supplemental

jurisdiction over all state-law claims pursuant to 28 U.S.C. § 1367 and 28 U.S.C. § 1338(b).

17. Venue is proper in this district under 28 U.S.C. § 1391.

18. Defendant Hologenix is domiciled in California and the Central District of California because its headquarters is located Los Angeles County (Santa Monica, California).

19. Upon information and belief, Hologenix engages in advertising and promotion of Celliant from its headquarters in California.

III. HOLOGENIX'S FALSE AND MISLEADING ADVERTISING CAMPAIGN

A. The "FDA-Approved" Statements

20. Celliant is not FDA approved. But since July 2017, Hologenix has been making false "FDA-approved" statements. These statements have been widely repeated by Hologenix's manufacturing partners and the press.

21. On July 31, 2017, Hologenix began promoting Celliant as "*FDA-approved*." Hologenix tweeted and wrote on Facebook, "What are you waiting for? Celliant is now FDA-approved, get your products today!" Celliant, Twitter (July 31, 2017, 10:30AM), https://twitter.com/Celliant/status/892014578854498304; Celliant, Facebook (July 31, 2017), https://www.facebook.com/Celliant/posts/10154892644672817.

22. On August 10, 2017, Hologenix posted a Facebook post and two Twitter posts that read in part: "We're still as pumped about this news as we were the day

it happened. #FDAapproval." Celliant, Twitter (Aug. 10, 2017 7:40AM), https://twitter.com/Celliant/status/895656022299336704; Celliant, Twitter (Aug. 10, 2017 2:46PM), https://twitter.com/Celliant/status/895763187513077760; Celliant, Facebook (Aug. 10, 2017), https://www.facebook.com/Celliant/posts/10154919569962817.

23. In an August 28, 2017 *Huffington Post* article, Hologenix co-founder and co-president Seth Casden said, "The approval that we have now is strictly for healthy people and we need to continue to do more testing and work, [and make] submissions with the FDA to ultimately get indications for the other population groups." Vivien Moon, *The Future of Health and Wellness Is A Responsive Textile*, Huffington Post, https://www.huffingtonpost.com/entry/the-future-of-health-and-wellness-is-a-responsive-textile_us_59a40712e4b0cb7715bfd720 (updated Aug. 28, 2017 1:41PM). The article's author further stated that "[i]n order to protect the consumer, the F.D.A. expresses that to make health related claims, companies must fulfill certain criteria proven by scientific research prior to being approved. A topic as serious as one's health puts pressure on the wellness industry which is why companies like Hologenix spend years working towards the necessary F.D.A. approval." *Id.*

24. Hologenix endorsed these statements by promoting and linking to the *Huffington Post* article on its website. *See The Future of Health and Wellness Is A Responsive Textile* (Aug. 26, 2017), https://celliant.com/blog/the-future-of-health-

and-wellness-is-a-responsive-textile/ (sharing a link to and republishing part of the *Huffington Post* article).

25. On September 26, 2017, Hologenix posted on Twitter, "Still so excited about this! #FDAapproval." Celliant, Twitter (Sept. 26, 2017 2:38PM), https://twitter.com/Celliant/status/912793542023536640. That post retweeted another user's post that read in part, "With #FDA approval, @Celliant is feeling energized." *Id.*

26. On October 16, 2017, Hologenix reminded manufacturers and consumers, "We're still buzzing over the news from this summer! #FDAapproved." Celliant, Twitter (Oct. 16, 2017 7:40AM), https://twitter.com/Celliant/status/919935971625336832; Celliant, Twitter (Oct. 16, 2017 8:00AM), https://twitter.com/Celliant/status/919941034834059264; Celliant, Facebook (Oct. 16, 2017), https://www.facebook.com/Celliant/posts/10155087076382817.

27. A February 22, 2018 article on *Inc.* magazine's website reported, "Amerisleep CEO Firas Kittaneh . . . sells . . . eco-friendly American-made [mattresses] that incorporate the FDA-approved sleep-enhancing fabric Celliant." Sonya Mann, *How to Get E-Commerce Customers to Spend a Lot of Money at Once (and Then Do It Again)*, Inc. (Feb. 22, 2018), https://www.inc.com/sonya-mann/expensive-ecommerce-shopping.html.

28. A June 27, 2018 *Hunker* article highlighting features of blankets wrote that the "[Infinity Blanket] is made with Celliant fibers, which are FDA approved."

7 Blankets That Do More Than Just Blanket, Hunker (June 27, 2018), https://www.hunker.com/13713636/7-blankets-that-do-more-than-just-blanket.

29. A July 18, 2018 *Shape* article about Under Armour clothes incorporating Celliant has the subheadline "The styles were designed with a new FDA-approved 'bioceramic' technology, which uses infrared energy to help boost strength, stamina, and recovery." Macaela Mackenzie, *This New Under Armour Athleisure Collection Is All About Recovery*, Shape (July 18, 2018), https://www.shape.com/fitness/clothes/under-armour-athleisure-collection-recovery-workout-clothes. The *Shape* article further states, "The new collection is made with a specially woven fabric called Celliant—an FDA-approved technology that uses a blend of minerals woven invisibly into the fabric to reflect your body's natural heat back to you as infrared light."

30. A July 18, 2018 *WWD Digital Daily* article about Under Armour clothes similarly states, "Hologenix worked on its process for 16 years and received Food and Drug Administration approval in summer 2017 for Celliant, which has been designated a medical device and general wellness product." Jean E. Palmieri, *Après Workout*, WWD Digital Daily (July 18, 2018), https://www.pressreader.com/usa/wwd-digital-daily/20180718/281496457063760.

31. An August 27, 2018 article in *Gear Patrol* stated, "[Celliant is] also FDA-Approved as a medical device, which is pretty unusual. . . . It was approved back in July of 2017, and at that point was in Salewa jackets, Tecnica ski boots, Xcel full wetsuits and Lumen sheets; a pretty wide variety of products." Meg

Lappe, *This Material You've Never Heard of Is Taking Over Activewear*, Gear Patrol (Aug. 27, 2018), https://gearpatrol.com/2018/08/27/celliant-technology-what-is-it/.

32. An August 31, 2018 product review for the "Infinity Blanket" states that the blanket "increases blood flow (which helps with energy, strength, and endurance) through FDA-approved Determined [sic] Celliant technology." TPM Shop, *Wrap Yourself in Wellness With This Infinity Blanket,* Talking Points Memo (Aug. 31, 2018 1:33AM), https://talkingpointsmemo.com/sourced/wrap-yourself-in-wellness-with-this-infinity-blanket.

33. An undated article on *Mattress Clarity* states, "[Celliant] has been through nine clinical trials, and is FDA-approved." Joe Auer, *How Does Celliant Work?*, Mattress Clarity, https://www.mattressclarity.com/blog/how-does-celliant-work/ (last visited Feb. 20, 2019).

34. A listing on Pillows.com includes the following line in a product description: "The PureCare® SuperSoft Celliant Sateen Sheet Set Queen Size are FDA APPROVED." PureCare® SuperSoft Celliant Sateen Sheet Set - Queen Size, *Pillows.com*, https://www.pillows.com/purecare-celliant-queen-.html. The specifications section of that listing reads, "**FDA:** FDA APPROVED." *Id.*

35. Hologenix's false assertions, as described above and made elsewhere, that Celliant is FDA-approved make their intended audience believe that Celliant is superior to other bioceramic materials on the market.

B. The "FDA-Determined" and Health Benefits Statements

36. In addition to falsely promoting Celliant as "FDA-approved," Hologenix uses the phrase "FDA-determined" to misleadingly suggest to manufacturers and consumers that the FDA not only has approved Celliant, but also has determined that Celliant actually has the purported health benefits advertised by Hologenix.

37. On July 25, 2017, Hologenix published a press release in which it announced:

> Hologenix, LLC, maker of Celliant, the world's most advanced, clinically tested responsive textile technology, announced today that the U.S. Food and Drug Administration (FDA) has determined Celliant products are medical devices and general wellness products, as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act. According to the FDA, Celliant products were determined to be medical devices because they temporarily promote increased local blood flow at the site of application in healthy individuals.

Press Release, Hologenix, LLC, U.S. FDA Determines Celliant® Responsive Textile Products Meet Criteria as Medical Devices and General Wellness Products, PR Newswire (July 25, 2017), https://www.prnewswire.com/news-releases/us-fda-determines-celliant-responsive-textile-products-meet-criteria-as-medical-devices-and-general-wellness-products-300493298.html. *See* Exh. A. In the same press release, Hologenix touted that products with Celliant were "clinically proven" to "increase energy, endurance, stamina and performance . . . recover faster from physical activity. . . [and] promote restful sleep and increased comfort." *Id.*

38. That same day, Celliant advertised on Facebook: "The U.S. Food and Drug Administration has determined Celliant products are medical devices and

general wellness products because they promote increased local blood flow at the site of application in healthy individuals. #Pumped." Celliant, Facebook (July 25, 2017), https://www.facebook.com/Celliant/photos/a.10150116690932817.277309.226448067816/10154876779297817/?type=3.

39. Hologenix has repeated its "FDA-determined" and health benefits statements throughout its website and on social media, and has encouraged its manufacturing partners to make the same misleading statements.

40. Hologenix currently states on its website:

> FDA Determined Medical Device and General Wellness Product.
>
> Meet The Future Of Performance Fabrics + Responsive Textiles.
>
> Celliant is a revolutionary, patented technology that harnesses and recycles the body's natural energy through the medium of fibers. Celliant's applied science utilizes a blend of minerals and proprietary ingredients that are embedded into the core of the fiber. Use of products containing this technology has been clinically proven to enhance tissue oxygen levels [and] improve athletic performance, sleep quality, health and wellness. Fibers, yarns and fabrics with Celliant technology can be found in some of the world's most recognized name brands.

Celliant, https://celliant.com/ (last visited Feb. 20, 2019). Those claims are followed by icons titled "Increase Circulation," "Cell Recovery," "Temperature Regulation," "Better Sleep," "Overall Wellbeing," and "Lifetime Durability." *Id.*

41. Hologenix also currently states on its website: "Infrared energy enhances cell function, which means injuries heal quicker, pain subsides faster, and stamina and endurance are amplified." *Sleep Better & Recharge*, Celliant, https://celliant.com/sleep/ (last visited Feb. 20, 2019).

42. Hologenix's website currently states that Celliant will cause you to "[t]ranslate hard work and persistence into increased blood flow that enables enhanced cellular performance, increased blood oxygen levels, and ultimately higher levels of cognitive focus and physical energy." *A Fabric to Take You Further*, Celliant, https://celliant.com/perform (last visited Feb. 20, 2019).

43. On December 6, 2017, the Cotton Council International put out a press release in which a Hologenix business development manager said, "[W]e're now an FDA-determined medical device so you can say on your packaging your product increases blood flow and energy, boosts performance and speeds muscle recovery." Press Release, *Revolutionary Cotton-Rich Yoga Wear Reduces Recovery Time With FDA-Determined Medical Device Celliant Technology Debuts at Première Vision Show*, Cotton USA (Dec. 6, 2017), https://cottonusa.org/news/2017/revolutionary-cotton-rich-yoga-wear-reduces-recovery-time.

44. Hologenix drew further attention to this statement by posting a link on its website to a news article that covered the press release. *See Celliant Selected by Cotton USA*, Celliant (Dec. 14, 2017), https://celliant.com/blog/celliant-selected-by-cotton-usa.

45. On July 28, 2017, Hologenix partner Draper Therapies wrote that Celliant was "clinically proven to," among other things, provide "Better/More Endurance," "Enhance/Increase Performance," "Increase/Enhance/More Speed," and "Promote restful sleep." Press Release, *Draper Therapies Happy to Announce*

US FDA Has Determined Celliant® Products Are Medical Devices and General Wellness Products, Draper Therapies (July 28, 2017), https://www.drapertherapies.com/2017/07/28/fda-determined-celliant-products-are-medical-devices. In that same press release, Draper Therapies product manager Becky Shipps stated that the FDA's "determination" "lends credence" to the efficacy of Celliant: "Our customers and anyone who has used Celliant knows that it works, but this just lends credence to our experience." *Id.*

46. Also in 2017, Hologenix partner Bear Mattress issued a press release after Hologenix's press release regarding the FDA's "determination" that stated, "We're pleased to see Celliant's clinically proven claims further substantiated by the FDA, and have already experienced increased consumer buying confidence. . . . The effect of Celliant is clinically proven to help the body increase energy, endurance, stamina and performance, recover faster from physical activity, and promote restful sleep and increased comfort." Press Release, *Benefits of Bear Mattress Reinforced by Recent FDA Designation of Celliant®* (2017), https://cdn.shopify.com/s/files/1/0661/5815/files/Bear_CELLIANT.pdf?5718024412153093489.

47. On November 4, 2017, on its Twitter feed, where Hologenix had promoted Celliant as "FDA approved" and "FDA determined," Hologenix linked to a Sleepopolis article that stated that "**[f]aster healing and pain relief** are just a couple of the major benefits Celliant creates through this improved oxygenation..." *See* Celliant, Twitter (Nov. 4, 2017 1:46PM),

https://twitter.com/Celliant/status/926913464890773504; Sleepopolis Team, *What Is Celliant Fiber?,* Sleepopolis, https://sleepopolis.com/blog/celliant-what-is-celliant-fiber (emphasis in original).

48. On April 14, 2018, Hologenix posted on its Twitter feed a link to a *Fast Company* article, which asserts in bold text: "**The benefits of Celliant have been clinically tested, since the product is regulated by the FDA.**" *See* Celliant, Twitter (Apr. 14, 2018 10:02AM), https://twitter.com/Celliant/status/985201730035027968; Elizabeth Segran, *These High-Tech Pajamas Are Proven to Help Your Post-Workout Recovery*, Fast Company (Apr. 3, 2018), https://www.fastcompany.com/40553388/these-high-tech-pajamas-are-proven-to-help-your-post-workout-recovery (emphasis in original).

49. On June 14, 2018, Hologenix shared a link to fabric vendor CF Stinson's June 11, 2018 Facebook post asserting that the FDA "designated" Celliant as a medical device because it was "[s]o effective." *See* Celliant, Facebook (June 14, 2018), https://www.facebook.com/Celliant/posts/10155686107192817, linking to CF Stinson, Facebook (June 11, 2018), https://www.facebook.com/cfstinson/posts/1842594969117622 ("So effective, Celliant® is designated as a medical device by the FDA.").

50. On October 17, 2018, on Celliant.com, where Hologenix has promoted Celliant as an "FDA determined medical device and general wellness product," Hologenix linked to an article stating that Celliant "restore[s] muscle tissue." *See Under Armour: 'We Make People Better,'* Celliant (Oct. 17, 2018),

https://celliant.com/blog/under-armour-we-make-people-better/; Grace Whelan, *Under Armour: 'We Make People Better,'* Drapers (Oct. 12, 2018), https://www.drapersonline.com/news/under-armour-were-here-to-make-our-people-better/7032566.article.

51. On October 28, 2018, on its Facebook page, where Hologenix had promoted Celliant as "FDA approved" and "FDA determined," Hologenix wrote, "Use of products containing Celliant technology has been clinically proven to enhance tissue oxygen levels [and] improve athletic performance, sleep quality, health and wellness." Celliant, Facebook (Oct. 28, 2018), https://www.facebook.com/Celliant/photos/a.10150116690932817/10155978539257817.

52. Hologenix partner Bare Ultrawarmth wrote: "Celliant is scientifically proven and FDA-determined to conserve body heat and accelerate thermal recovery." *Bare Ultrawarmth 3mm Scuba Diving Dive Snorkeling Gloves*, Walmart, https://www.walmart.com/ip/Bare-Ultrawarmth-3mm-Scuba-Diving-Dive-Snorkeling-Gloves/531019045 (last visited Feb. 20, 2019).

53. Hologenix partner Under Armour promotes Celliant-containing products as follows: "Products powered by Celliant have been determined by the FDA to increase localized circulation, leading to faster recovery." Athlete Recovery Compression™, Under Armour, https://www.underarmour.com/en-us/mens-athlete-recovery-compression-leggings/pid1318387-001 (last visited Feb. 20, 2019).

54. The above statements are all false or misleading.

55. Celliant is not registered as a medical device with the FDA.

56. Hologenix's claims about the purported health benefits of products that incorporate Celliant have not been reviewed by the FDA to determine their validity.

57. The FDA did not determine that Celliant in fact has the health benefits claimed by Hologenix and its partners.

58. MET brings this action to stop Hologenix's false and deceptive advertising, for disgorgement of Hologenix's ill-gotten gains, and to be compensated for the millions of dollars it has lost because of Hologenix's unlawful conduct.

IV. HOLOGENIX'S FDA "APPROVED" STATEMENTS ARE FALSE

59. As described in paragraphs 20-34 above, beginning in July 2017, Hologenix started promoting Celliant as "FDA-approved."

60. Celliant is not an FDA-approved medical device.

61. Celliant is not listed on the FDA's list of approved medical devices.

62. Hologenix has not registered Celliant as a medical device.

63. Mere classification of a product as a medical device by the FDA does not mean that the product is an FDA-approved medical device.

64. A medical "device" for purposes of the Federal Food, Drug, and Cosmetic ("FD&C") Act includes any article that is "intended to" affect the structure or any function of the body, or "*intended for* use in the diagnosis of

disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease. . . ." 21 U.S.C. § 321(h) (emphasis added).

65. Any manufacturer may seek the FDA's view as to whether its product is a medical device.

66. Specifically, Section 513(g) of the FD&C Act (21 U.S.C. § 360c(g)) provides a means for obtaining the FDA's views about whether a product is a medical device, and the likely classification and regulatory requirements applicable to a particular device. The FDA has explained that it does not evaluate the safety or effectiveness of a device in response to a Section 513(g) request or provide approval for marketing:

> FDA does not review data related to substantial equivalence or safety and effectiveness in a 513(g) Request for Information. FDA's responses to 513(g) Requests for Information are not device classification decisions and do not constitute FDA clearance or approval for marketing. Classification decisions and clearance or approval for marketing require submissions under different sections of the FD&C Act.

FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act (Apr. 6, 2012), https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm209851.pdf (updated Dec. 21, 2015).

67. The specific class of a medical device is important because each class generally corresponds to three different levels of FDA scrutiny:

> Class III devices are high-risk, or novel, devices and most require direct demonstration of safety and effectiveness through the [premarket approval] pathway. Class II devices present moderate risks to patients; in most cases,

> manufacturers must submit [premarket notifications] before marketing. Class I devices are low-risk and most are currently exempted from any premarket review; they are subject only to rudimentary controls such as product listing and labeling.

Jonas Zajac Hines et al., *Left to Their Own Devices: Breakdowns in United States Medical Device Premarket Review*, PLoS Med. (July 2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2903853/ (footnote omitted).

68. Hologenix claims in its advertising that Celliant is a Class I medical device. For example, in a press release on its website, Hologenix states: "In addition to the United States, Celliant is designated as a Class I medical device in Canada, European Union, Australia and New Zealand." https://www.prnewswire.com/news-releases/us-fda-determines-celliant-responsive-textile-products-meet-criteria-as-medical-devices-and-general-wellness-products-300493298.html. *See* Exh. A.

69. As explained by the Government Accountability Office, examples of Class I medical devices include tongue depressors, elastic bandages, reading glasses, and forceps. GAO, *Medical Devices: FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved Through the Most Stringent Premarket Review Process* (Jan. 2009), https://www.gao.gov/new.items/d09190.pdf; *see also Is the Product a Medical Device?*, FDA, https://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051512.htm (last updated Mar. 22, 2018) ("Medical devices range from simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices.").

V. THE FDA HAS NOT APPROVED CELLIANT AS A GENERAL WELLNESS PRODUCT

70. As described in paragraphs 36-53 above, Hologenix has promoted Celliant as an FDA-approved general wellness product.

71. Celliant is not an FDA-approved general wellness product.

72. The FDA has largely declined to exercise oversight over general wellness products. A general wellness product is not subject to FDA oversight unless the manufacturer makes specific claims about specific illnesses or the device is invasive or implanted or poses a safety risk.

73. The FDA has defined a general wellness product as a product that "has (1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity or (2) an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition." FDA, *General Wellness: Policy for Low Risk Devices* (July 29, 2016), https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm429674.pdf. The FDA has stated that it "does not intend to examine low risk general wellness products to determine whether they are devices within the meaning of the FD&C Act. . . ." *Id.*

VI. HOLOGENIX'S "FDA-DETERMINED" STATEMENTS ARE MISLEADING

74. As described in paragraphs 36-53 above, beginning in July 2017, Hologenix has repeatedly stated that the "FDA determined" that Celliant provides certain health benefits.

75. The FDA has not determined that products incorporating Celliant in fact have the health benefits claimed by Hologenix.

76. Hologenix's advertising campaign alternates between "FDA-approved" and "FDA-determined" and links its "FDA-determined" statements to specific health claims, suggesting that the FDA validated its health claims.

77. Additionally, because consumers are not generally familiar with FDA terminology, Hologenix's use of "FDA determined" could be interpreted by reasonable consumers to mean the same thing as "FDA-approved," even when it is not connected to a health benefit.

78. The combined effect of the claims made in this campaign can be seen in the statements made by Hologenix's manufacturer partners and sophisticated industry journalists whom Hologenix has deceived, such as those described in paragraphs 43-53 above.

79. Hologenix's manufacturer partners have been misled by the false and misleading claims regarding Hologenix's interactions with the FDA, as noted above.

80. Hologenix has intentionally created a cycle of false and deceptive representations about Celliant that have caused manufacturers and journalists to believe that the FDA has approved Celliant or validated Celliant's purported health benefits and to promote Celliant with statements conveying their mistaken understanding, which Hologenix shares and links on its website.

VII. HOLOGENIX'S ESTABLISHMENT CLAIMS ARE FALSE AND MISLEADING

81. Hologenix makes establishment claims about the purported health benefits of Celliant, *i.e.*, claims that tests prove or establish the effectiveness of Celliant in providing health benefits.

82. For example, the press release published by Hologenix on July 25, 2017, stating that products with Celliant were "clinically proven" to "increase energy, endurance, stamina and performance … recover faster from physical activity … [and] promote restful sleep and increased comfort." *See* Exh. A.

83. Another example is the October, 2018 Facebook post by Hologenix stating that "Use of products containing Celliant technology has been clinically proven to enhance tissue oxygen levels [and] improve athletic performance, sleep quality, health and wellness." Celliant, Facebook (Oct. 28, 2018), https://www.facebook.com/Celliant/photos/a.10150116690932817/10155978539257817.

84. These establishment claims regarding the purported health benefits of Celliant are false and misleading. They are not supported by competent and reliable tests of products containing Celliant.

VIII. HOLOGENIX'S ADVERTISING CAMPAIGN IS HARMING MET

85. MET is a direct competitor of Hologenix.

86. Like Hologenix, MET promotes and sells its bioceramic material to apparel, bedding, and other textile manufacturers.

87. As described in greater detail below, after Hologenix started its campaign of false and misleading statements, two manufacturers—Under Armour Inc. and American Textile Company—switched to Hologenix after working with MET for years.

A. Under Armour

88. Beginning in 2014 and through 2017, Under Armour and MET entered into a series of agreements to allow Under Armour to manufacture and sell products "Powered by Redwave."

89. In early January 2017, Under Armour introduced athlete recovery sleepwear that it manufactured using Redwave at CES (formerly the "International Consumer Electronics Show") in Las Vegas, Nevada.

90. The introduction at CES generated significant publicity. Even Hologenix took notice. Hologenix tweeted about the new Under Armour Far Infrared apparel in January of 2017. *See* Celliant, Twitter (Jan. 7, 2017 3:46PM), https://twitter.com/Celliant/status/817880001202847744.

91. In April 2017, Hologenix again tweeted about the Under Armour athlete recovery sleepwear. Hologenix misleadingly suggested that Hologenix produced the sleepwear by using its hashtag "#Celliant." *See* Celliant, Twitter (Apr. 24, 2017 9:16AM), https://twitter.com/Celliant/status/856542409563537408.

92. Following CES, MET and Under Armour started negotiating a three-year deal under which Under Armour would pay MET a minimum of $2,500,000 per year to allow Under Armour to be the exclusive manufacturer of sleepwear incorporating Redwave plus royalties for each unit sold, and would make a separate payment for each kilogram of Redwave used.

93. In order to ensure Under Armour did not run out of Redwave powder while the parties negotiated the long-term supply contract, Under Armour and Hologenix entered into a short-term exclusive supply agreement. The parties' exclusivity remained in effect until either of the parties executed a superseding agreement or one party provided notice to the other that it desired to end the exclusivity.

94. During the negotiation of both the short-term and long-term supply contracts, Under Armour made clear that it wanted to make claims about the health benefits of Under Armour products incorporating bioceramic materials in the advertisement and promotion of such products.

95. After MET and Under Armour exchanged multiple drafts of the intended superseding long-term exclusive supply contract, in or around June of 2017, Under Armour went silent.

96. MET made multiple inquiries about the status of discussions but received no response.

97. Upon information and belief, in the first half of 2017, Hologenix tried to convince Under Armour to work with Hologenix instead of MET.

98. As described above, on July 25, 2017, Hologenix announced in a press release that "the U.S. Food and Drug Administration has determined Celliant products are medical devices and general wellness products … because they temporarily promote increased local blood flow at the site of application in healthy individuals[,]" and it started promoting Celliant on social media and in the press as "FDA approved." *See* Exh. A.

99. Less than one week later, by letter dated July 31, 2017, Under Armour informed MET that it was terminating the exclusivity provision of the parties' short-term supply contract.

100. MET now knows that Hologenix entered into an exclusive deal with Under Armour for the supply of MET's Celliant bioceramic material.

101. Upon information and belief, Hologenix knew that if it promoted Celliant as "FDA-approved" or an "FDA-determined" medical device and wellness product with statements about its supposed health benefits, it was substantially certain or, at a minimum, foreseeable that Under Armour would abandon its existing bioceramic sleepwear partner, MET.

102. Upon information and belief, Hologenix is indemnifying Under Armour for FDA- and health-related claims about Celliant in connection with the promotion of Under Armour Athlete Recovery Sleepwear incorporating Celliant.

103. Upon information and belief, Hologenix's willingness to make FDA- and health-related claims about Celliant made Celliant more attractive to Under Armour than Redwave was.

104. Hologenix promotes Under Armour's products on Celliant.com where it also promotes Celliant with the false and misleading statements described above.

B. American Textile

105. MET lost not only Under Armour's business because of Hologenix's false and misleading promotional campaign about Celliant, but also American Textile's business as well.

106. American Textile makes bedding. MET and American Textile had contracted to create bedding that incorporated Redwave.

107. MET began its relationship with American Textile in 2015. MET entered into a series of contracts with American Textile. This included a May 4, 2016 Evaluation and Supply Agreement.

108. The Evaluation and Supply Agreement granted American Textile an option to incorporate Redwave powder into its products.

109. American Textile exercised its option on April 3, 2017. The Evaluation and Supply Agreement had an initial term of 18 months after American

Textile received the Redwave supply, and subsequently would renew for successive one-year periods unless either party terminated by written notice.

110. At this time, American Textile also was working with Under Armour in connection with Athletic Recovery Sheets.

111. Shortly after American Textile exercised its option with MET, American Textile told MET that Hologenix was touting its "FDA approval for Celliant." American Textile asked how MET could compete against that claim.

112. After Under Armour announced its exclusive deal with Hologenix, MET had a conversation with an executive at American Textile about continuing to work together.

113. The American Textile executive demurred, stating that Under Armour insisted that American Textile work with Hologenix instead of MET, and that American Textile could not pass up the opportunity to continue to work with Under Armour.

114. The American Textile executive said that Under Armour switched to Hologenix because Under Armour could use Hologenix's promotional statements without restrictions and Under Armour would be indemnified for its use of those statements.

115. On July 31, 2018, American Textile sent a termination notice to MET, stating that the Evaluation and Supply Agreement would be terminated on October 3, 2018.

COUNT I

VIOLATION OF THE LANHAM ACT (15 U.S.C. § 1125(a)(1)(B))

116. MET repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

117. Hologenix's activities as described above constitute false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

118. Hologenix has made and, if not enjoined, will continue to make false and misleading descriptions of fact or representations of fact about the characteristics or qualities of Celliant in commercial advertising or promotion in interstate commerce by and through its website, social media posts, and other marketing and promotional materials.

119. Hologenix's statements as described herein are commercial advertising about its product Celliant.

120. Hologenix caused its statements about Celliant and products that incorporate Celliant to travel in interstate commerce.

121. Hologenix's false and misleading statements have actually deceived and/or have a tendency to deceive a substantial segment of their intended audience. The tendency of Hologenix's statements to deceive is evident from the way Celliant has been described in the press and by Hologenix's business partners.

122. Hologenix's statements about Celliant have influenced and are likely to influence manufacturers to enter into partnerships with Hologenix to the

detriment of MET, and influence the purchasing decisions of consumers who are shopping for "recovery" garments and textiles.

123. As a result of Hologenix's false advertising for Celliant, MET lost business with at least Under Armour and American Textile.

124. By reason of the foregoing, Hologenix has intentionally and willfully violated 15 U.S.C. § 1125(a)(1)(B).

125. As an actual and proximate result of Hologenix's conduct described herein, MET has suffered monetary damages in an amount to be proven at trial.

126. Hologenix's aforesaid acts also have caused, and unless restrained and enjoined by this Court, will continue to cause irreparable damage, loss, and injury to MET in the form of loss of manufacturer and consumer goodwill for which MET has no adequate remedy at law. MET is entitled to an injunction, pursuant to 15 U.S.C. § 1116(a), to prevent Hologenix from continuing to make the false and misleading representations, and to correct the false impression left by Hologenix's deception.

127. MET is entitled, pursuant to 15 U.S.C. § 1117, to recover from Hologenix: (i) Hologenix's profits from its false advertising, (ii) damages MET has sustained due to Hologenix's conduct, and (iii) the costs of this action.

128. Because this is an exceptional case involving calculated and willful misconduct by Hologenix, MET is also entitled, pursuant to 15 U.S.C. § 1117(a), to recover (i) up to three times the amount of actual damages and (ii) attorneys' fees.

COUNT II

INTENTIONAL INTERFERENCE WITH ECONOMIC ADVANTAGE

129. MET repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

130. MET had economic relationships with Under Armour and American Textile. These economic relationships contained the probability of future economic benefit to MET.

131. Specifically, MET was engaged in extensive negotiations with Under Armour after the introduction of the athlete recovery sleepwear at CES 2017.

132. Hologenix knew of the existence of MET's relationship with Under Armour.

133. Upon information and belief, Hologenix sought to disrupt MET's relationship with Under Armour.

134. Upon information and belief, Under Armour withdrew from negotiations with MET and ultimately terminated its relationship with MET only after Hologenix started promoting Celliant with the FDA- and health-related false and misleading statements and agreed to indemnify Under Armour if Under Armour wanted to repeat those statements.

135. MET and American Textile had a contractual relationship, and MET had a reasonable expectation that the relationship would continue.

136. Upon information and belief, Hologenix knew of the existence of MET's relationship with American Textile through its knowledge of the

relationship among MET, Under Armour, and American Textile and because MET's dealings were well known in the small industry in which MET and Hologenix compete.

137. American Textile terminated its contract with MET because it wanted to continue working with Under Armour and Under Armour would only work with Hologenix because of Hologenix's FDA-related statements and willingness to indemnify Under Armour for those same statements.

138. Had American Textile not terminated its contract with MET, the contract would have auto-renewed.

139. Hologenix intentionally committed wrongful acts when it engaged in a campaign of false advertising. These acts are independently wrongful because they violate the Lanham Act and California's False Advertising Law, Cal. Bus. & Prof. Code § 17500 et seq.

140. Hologenix's intentionally wrongful false advertising campaign was designed to disrupt and did disrupt MET's relationships with Under Armour and American Textile.

141. Under Armour stopped negotiating the exclusive arrangement with MET.

142. American Textile gave notice of nonrenewal of its contractual relationship with MET.

143. MET suffered economic harm when it lost the millions of dollars of revenue that it would have received under its prospective relationships with Under Armour and American Textile.

144. As a result of Hologenix's improper conduct, MET suffered actual damages in an amount to be determined at trial.

145. Hologenix's conduct as described herein amounts to oppression, fraud, and malice, thereby warranting the imposition of punitive damages in order to punish Hologenix and to deter Hologenix from similar, future misconduct.

COUNT III

NEGLIGENT INTERFERENCE WITH ECONOMIC ADVANTAGE

146. MET repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

147. MET had economic relationships with Under Armour and American Textile. These economic relationships contained the probability of future economic benefit to MET.

148. Specifically, MET was engaged in extensive negotiations with Under Armour for a long-term supply contract, and MET had a supply contract with American Textile that was set to auto-renew.

149. Hologenix knew of the existence of MET's relationship with Under Armour.

150. Hologenix knew of the existence of MET's relationship with American Textile.

151. Hologenix owed MET a duty of care because it was foreseeable that if Hologenix did not act with due care in its advertising and promotion of Celliant, its actions would interfere with the relationship between MET and its manufacturer partners, including Under Armour and American Textile, and cause MET to lose the future economic benefit or advantage of those relationships.

152. Hologenix breached this duty when it engaged in a campaign of false advertising.

153. Hologenix's false advertising campaign is independently wrongful because it violates the Lanham Act and California's False Advertising Law, Cal. Bus. & Prof. Code § 17500 et seq.

154. As a proximate result of Hologenix's false advertising campaign, Under Armour and American Textile terminated their relationships with MET.

155. As a result of Hologenix's interference, MET has lost millions of dollars of revenue that it would have received from these anticipated contracts.

156. As a result of Hologenix's improper conduct, MET suffered actual damages in an amount to be determined at trial.

157. Hologenix's conduct as described herein amounts to oppression, fraud, and malice, thereby warranting the imposition of punitive damages in order to punish Hologenix and to deter Hologenix from similar, future misconduct.

JURY DEMAND

MET demands a jury trial as to all issues that are triable by a jury in this action.

PRAYER FOR RELIEF

WHEREFORE, MET respectfully requests that this Court enter judgment against Hologenix as follows:

a. Issuing a preliminary and permanent injunction ordering that Hologenix and its agents, employees, or representatives, and all persons acting in concert or participating with it, are commanded, enjoined, or restrained, directly or indirectly, by any means whatsoever, from falsely using in commerce or causing to be published or otherwise disseminated in any form of promotional materials or activities any false or misleading representation concerning Celliant;

b. Issuing a permanent injunction ordering that Hologenix engage in appropriate corrective advertising at its own expense, reasonably designed to reach all persons to whom the false and misleading statements made by Hologenix were directly or indirectly disseminated, and retracting the false and misleading statements previously made;

c. Awarding MET:

i. Damages in an amount to be proven at trial, such damages to be trebled pursuant to 15 U.S.C. § 1117;

ii. All of Hologenix's profits derived by reason of the unlawful acts complained of above, such damages to be trebled pursuant to 15 U.S.C. § 1117;

iii. Punitive damages as appropriate to deter any future oppression, malice, and fraud by Hologenix in disregard of MET's rights;

iv. Pre- and post-judgment interest on the foregoing sums;

d. Ordering Hologenix to pay MET's reasonable attorneys' fees, costs and disbursements of this action; and

e. Granting such further and other relief as the Court deems just and proper.

Dated: February 28, 2019

MANATT, PHELPS & PHILLIPS, LLP
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